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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,631	12/31/2003	Heinz-Werner Kleemann	DEAV2002/0094 US CNT	8300

5487 7590 09/08/2006

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EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/749,631	<b>Applicant(s)</b> KLEEMANN ET AL.	
	<b>Examiner</b> Rebecca L. Anderson	<b>Art Unit</b> 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.  
4a) Of the above claim(s) 7-19,21-32 and 34-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,20 and 33 is/are rejected.
- 7) ☒ Claim(s) 1-6,20 and 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-48 are currently pending in the instant application. Claims 7-19, 21-32 and 34-48 are withdrawn from consideration as being for non-elected subject matter, claims 1-6, 20 and 33 are objected and claims 1, 2, 5, 6, 20 and 33 are rejected.

### ***Election/Restrictions***

As stated in the previous office action, **the elected invention for search and examination is:**

The products of the formula (I) wherein **R1, R2, R3,n, Ra, Rb** and **R4** are as found in claim 1 and **Ar** is 7H-pyrrolo-[2,3-d]-pyrimidine, which may be linked via any of its positions and which is substituted in at least one of its positions by alkyl having 1, 2, 3, 4, 5 or 6 carbon atoms, halogen, nitro, NRaRb, alkylcarbonylamino having 1,2,3 or 4 carbon atoms, hydroxyl, alkoxy having 1,2,3,4,5 or 6 carbon atoms, S(O)<sub>n</sub>R4, Co2H, alkoxycarbonyl having 1, 2, 3, 4, 5 or 6 carbon atoms, alkylcarbonyl having 1,2,3,4,5 or 6 carbon atoms, CONRaRb, CN, polyfluoroalkyl having 1,2,3 or 4 carbon atoms, polyfluoroalkoxy having 1,2 or 3 carbon atoms or SO3H, or a racemic mixture, enantiomer, diastereomer, or tautomer of such compound, or a mixture thereof, or a pharmaceutically acceptable salt of such compound, racemic mixture, enantiomer, diastereomer, tautomer, or mixture.

The requirement is still deemed proper and is therefore FINAL.

### ***Response to Arguments***

Applicant's arguments filed 26 June 2006 have been fully considered but they are not persuasive. In regards to the elected invention for search and examination as

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identified supra, applicant argues that the restriction requirement is improper because it divides Applicants' Markush claim in contravention to the requirements of MPEP 803.02 and the case law, such as *In re Harnish*. These arguments are not persuasive as the restriction requirement was made under 35 USC 121. 35 USC 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. Rather, applicant has argued case law, however, these two decisions involved rejections of claims under 35 U.S.C. 121 and not a restriction as is the case herein.

So, here we have claims which involve more than one independent or distinct inventions. Under 35 USC 121, the claims may be restricted and the examination limited to a restricted invention. Accordingly, restriction as has been presented in this application is proper and the requirement to restrict is repeated and made final.

While applicant has requested that the claim objection be deferred pending resolution of the further restriction requirement, it is noted that the claim objection is maintained as the restriction requirement is deemed proper for the reasons set forth above.

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In regards to applicants' arguments of the 35 USC 103(a) rejection of the non-elected subject matter, it is noted that the rejection is withdrawn as it was merely cited to show the closest prior art found in the search and examination of the elected invention. As LANG et al. does not anticipate nor render obvious applicants' elected invention for search and examination, the rejection is withdrawn.

While applicant has requested that the double patenting rejection be deferred pending some identification of allowable subject matter, it is noted that the double patenting rejection is considered proper and is therefore maintained.

#### ***Maintained Claim Objections***

Claims 1-6, 20 and 33 are objected to as containing non-elected subject matter. Claims 1-6, 20 and 33 presented drawn solely to the elected invention identified supra wherein Ar is 7H-pyrrolo-[2,3-d]-pyrimidine would overcome this objection.

#### ***Maintained Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5, 6, 20 and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7, 21 and 34 of copending Application No. 10/749620 (see US Pre-Grant Publication 2005/0026989). Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants' elected invention of instant claims 1, 2, 5, 6, 20 and 33 are claiming compounds wherein Ar is a 7H-pyrrolo-[2,3-d]-pyrimidine, diagnostic agents and pharmaceutical compositions.

Conflicting claims 1, 2, 5, 6, 7, 21 and 34 are claiming compounds (conflicting claims 1 and 2), pharmaceutical compositions (conflicting claims 6 and 7) and diagnostic agents (conflicting claims 20 and 33) of the formula (I) wherein the positions

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equivalents to applicants R1, R2 and R3 are identical. However, the conflicting claims have the positions equivalent to the unsubstituted positions of applicants indole as hydrogen, alkyl having 1, 2, 3, 4, 5, or 6 carbon atoms, halogen, NraRb or polyfluoroalkyl having 1, 2, 3, or 4 carbon atoms (conflicting R2) and as hydrogen or halogen (conflicting R5). While the conflicting claims have Ar as a 9 or a 10 membered bicyclic heteroaryl having one, two or three nitrogen atoms in conflicting claim 1, a preference is found towards applicants' elected invention in conflicting claim 2 wherein Ar can be 7H-pyrrolo-[2,3-d]-pyrimidine. Preferences to conflicting R2 and R5 as hydrogen can be seen in conflicting claim 5 wherein the discloses species have R2 and R5 as hydrogen.

The difference between the claims at issue and the conflicting claims is that the compounds claimed in US application No. 10/749,630 generically overlap with applicants' instantly claimed elected invention. However, preferences are found in the conflicting claims for Ar as 7H-pyrrolo-[2,3-d]-pyrimidine and R2 and R5 as hydrogen.

Therefore, it would have been obvious to one of ordinary skill in the art, when faced with the conflicting claims of 10/749630 to prepare applicants' instantly claimed elected invention as the conflicting claims generically overlap with applicants' instantly claimed elected invention and have preferences towards Ar as 7H-pyrrolo-[2,3-d]-pyrimidine and R2 and R5 as hydrogen. The motivation would be the expectation of preparing additional products useful as diagnostic agents and pharmaceutical compositions for the treatment of, for example, metastasis.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Closest Art***

The closest prior art is LANG et al., US Patent No. 5,852,046. US Patent No. 5,852,046 discloses benzo-fused heterocyclic compounds having a 5-membered ring and their use as diagnostic agents and medicaments on column 1, lines 15-17. The benzo-fused heterocyclic compounds having a 5-membered ring are of the formula I wherein X can be N or CR(6); Y can be oxygen, S or NR(7); A and B together are a bond or are both hydrogen; one of the substituents R(1) to R(7) is  $-\text{CO}-\text{N}=\text{C}(\text{NH}_2)_2$ ; the other respective substituents R(1) to R(6) are such as H or (C1-6)alkyl; n is zero to 10; R(7) can be hydrogen or R(8)-CnH2n; and R(8) can be hydrogen, (C2-6)alkenyl, phenyl, 1- or 2-naphthyl, pyridyl, quinolyl or isoquinolyl (columns 1 and 2). Preferences towards the non-elected subject matter of applicants' instant invention are found in the preferences wherein Y is NR(7) (column 2, line 29); one of the substituents R(1) to R(6) is  $-\text{CO}-\text{N}=\text{C}(\text{NH}_2)_2$ ; A and B are a bond (column 2, line 30); n is zero to 4 (column 2, line 41); R(8) can be quinolyl or isoquinolyl (column 2, line 63). Further preferences to compounds which are positional isomers of the non-elected subject matter of the claimed invention are found in preferred embodiments on column 3 wherein X is CR(6); Y is NR(7); A and B together can form a bond; R(1) is  $-\text{CO}-\text{N}=\text{C}(\text{NH}_2)_2$ ; n can be zero; R(8) can be quinolyl or isoquinolyl; and R(9) can be R(8)-CnH2n. Further preferences are found on columns 3 and 4 wherein R(8) can be quinolyl or isoquinolyl and can be substituted by 1 to 3 substituents chosen from the group consisting of F, Cl, Br, I, CF3,



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etc. However, LANG et al. fails to anticipate or render obvious applicants instant elected invention for search and examination.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

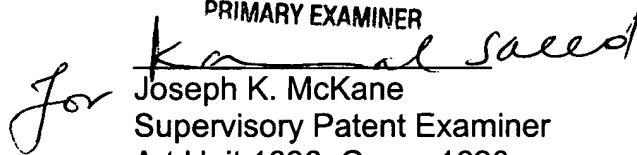
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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